Awareness Training

ISO 9001:2015

Quality Management System

&

ISO14001:2015

Environmental Management System

Awareness Training

Course objectives

- To be aware of the new concepts and requirements of ISO9001:2015 and ISO14001:2015
- How the new standards will affect the existing QEMS
- Prepare company for the transition

Agenda

- Documentation Structure for New Standards
- Process Approach
- New Terminology
- Key Changes
- Requirements of ISO9001:2015 Standard
- Requirements of ISO14001:2015 Standard

Documentation Structure for New Standards

High Level Structure (HLS)

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

Plan - 4, 5 & 6

Do - 7 & 8

Check - 9

Act -10

Introduction To

ISO 9001:2015 Standard

HISTORY AND BACKGROUND OF THE ISO 9001 STANDARD

- **1987 - The year in which the standard was first ratified (originated from BS5750)**
- **1994 - Second Edition**
- **2000 - Third Edition**
- **2008 - Fourth Edition**
- **2015 - Fifth Edition**

Relationship with Other Management System Standards

- **ISO 9000, Quality Management Systems - Fundamentals and Vocabulary**
- **ISO 9001, Quality Management Systems - Requirements**
- **ISO 9004, Managing for the sustained success of an organization – A quality management approach**

Cost Savings of Quality Management

Overall Cost ↓ =
Operating costs + Prevention costs ↑ +
Appraisal Costs + Failure Costs ↓ +
Profit

(Quality costs – prevention, appraisal and failure)

Cost of failure can be reduced by increasing prevention and getting it right first time.

Quality management principles

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision making
- Relationship management

QMP 1 Customer focus

Statement

The primary focus of Quality Management is to meet customer requirements and to strive to exceed customer expectations

Rationale

Sustained success is achieved when organization attracts and retains the confidence of customers and other interested parties. Every aspect of customer interaction provides an opportunity to create more value for customer. Understand current and future needs of customers and other interested parties contributes to sustained success.

QMP 2 Leadership

Statement

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the quality objectives

Rationale

Creation of unity of purpose, direction and engagement enable organization to align its strategies, policies, processes and resources to achieve its objectives

QMP 3 Engagement of people

Statement

It is essential for organization that all people are competent, empowered and engaged in delivering value. Competent, empowered and engaged people throughout the organization enhance its capability to create value

Rationale

To manage an organization effectively and efficiently, it is important to involve all people at all levels and to respect them as individuals. Recognition, empowerment and enhancement of skills and knowledge facilitate engagement of people in achieving objectives of organization

QMP 4 Process approach

Statement

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as coherent system

Rationale

QMS is composed of interrelated processes. Understanding how results are produced by this system, including its processes, resources, controls and interactions, allows organization to optimize its performance

QMP 5 Improvement

Statement

Successful organization have an ongoing focus on improvement

Rationale

Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities

QMP 6 Evidence-based decision making

Statement

Decisions based on analysis and evaluation of data and information are more likely to produce desired results

Rationale

Decision-making can be a complex process, and it involves some uncertainty. It involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause and effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decisions made

QMP 7 Relationship management

Statement

For sustained success, organization manage their relationships with interested parties, such as suppliers

Rationale

Interested parties influence performance of an organization. Sustained success is more likely to be achieved when an organization manages relationships with interested parties to optimize their impact on its performance. Relationship management with its supplier and partner network is often of particular importance

Process Approach

Process Approach

Process – set of interrelated or interacting activities which transforms inputs into outputs

* Refer to Company Process Flow Chart

Process approach

- Understanding and managing interrelated processes as a system contributes to the company's effectiveness and efficiency in achieving its intended results

- Helps company to control interrelationships and interdependencies among processes so that overall performance can be enhanced

Process approach

PDCA Cycle

- **Plan**- Establish objectives and resources needed to deliver results, identify and address risks and opportunities
- **Do**- Implement as planned
- **Check**- Monitor and measure processes & outputs and report the results
- **Act-** Take action to improve performance

Process approach

Risk-based thinking

Enable organization

- to determine the factors that could cause its processes and QMS to deviate from planned results
- to put in place preventive controls to minimize negative effects
- to make maximum use of opportunities as they arise

Risk-based thinking

- Organization needs to plan and implement actions to address risks and opportunities

- Addressing risks and opportunities establishes a basis for increasing the effectiveness of QMS, achieving improved results and preventing negative effects



New Terminology

Major differences in terminology

ISO9001:2008		ISO9001:2015
Products	-	**Products and services**
Documents /records	-	**Documented information**
Work environment	-	**Environment for operation of processes**
Purchased product	-	**Externally provided products and services**
Supplier	-	**External provider**

Terms and definitions

Context of organization – business environment, combination of internal and external factors and conditions that can have an effect on an organization's approach to its products, services and investments and interested parties

Terms and definitions

Interested party – person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity

eg customers, owners, staff, suppliers, bankers, unions, partners, society, competitors, pressure group, regulatory, contractors, consultants

Terms and definitions

Risk –

effect of uncertainty on an expected result

Quality –

degree to which a set of inherent characteristics of an object fulfils requirements (fitness for purpose)

Quality Products & Services

Characteristics – distinguished feature

- Aesthetics & good workmanship
- Functionality & durability
- Safety & integrity
- Within budget & timeframe
- Maintainability & Serviceability
- Conform with customer, legal, regulatory and other requirements eg SS, CP

Terms and definitions

External Provider (Supplier) → Organization → Customer

External provider – person or organization that provides a product or a service; can be internal or external

Customer – person or organization that could or does not receive a product or a services is intended for or required by this person or organization; can be internal or external

Key Changes in ISO9001:2015

Key Changes in ISO9001:2015

- The adoption of High Level Structure
- An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach
- More flexibility on documentation. More focus on documented information.
- A requirement to define the boundaries and applicability of the QMS
- A requirement to determine internal and external issues
- A requirement to determine needs and expectations of interested parties
- Increased leadership requirements

ISO 9001:2015 (New)

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

ISO 9001:2008 (Old)

1. Scope
2. Normative references
3. Terms and definitions
4. Quality management system
5. Management responsibility
6. Resource management
7. Product realization
8. Measurement, analysis and improvement

Key Changes in ISO9001:2015

* Refer to Appendix A

ISO 9001:2015

Quality Management Systems
- Requirements

Knowing ISO 9001 Clauses



4 Context of the organization

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the quality management system

4.4 Quality management system and its processes

4.1 Understanding the organization and its context

- **Shall determine external and internal issues that**
  - **are relevant to its purpose and strategic direction and**
  - **affects its ability to achieve intended results of its QMS**
- **Shall monitor and review information about these external and internal issues**

4.1 Understanding the organization and its context

External issues

– legal, technology, competitive market, cultural, social and economic environment whether international, national regional or local

Internal Issues

– values, culture, knowledge and performance of organization

4.1 Understanding the organization and its context

Determine external issues and internal Issues

* Refer to List of External and Internal Issues

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine the

a) interested parties
b) requirements of these parties

Shall monitor and review information about these interested parties and their requirements

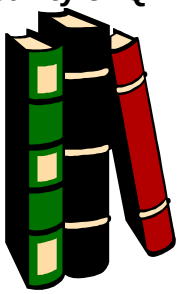
4.2 Understanding the needs and expectations of interested parties

Determine interested parties and their needs and expectations

* Refer to List of Interested Parties

4.3 Determining the scope of QMS

Shall determine the boundary and applicability of QMS to establish its scope



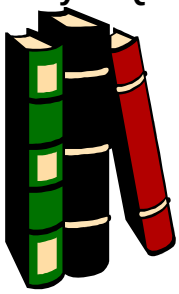
Shall consider

a) **external and internal issues**
b) **requirements of interested parties**
c) **its products and services**

Shall apply all requirements unless not applicable and maintain the scope as documented information. Provide justification for any requirements not included in QMS.

4.3 Determining the scope of QMS

Shall determine the boundary and applicability of QMS to establish its scope



* Refer to Company Scope of QMS

4.4 QMS and its processes

4.4.1 Shall establish, implement, maintain and continually improve its QMS including processes needed and their interactions, in accordance with the requirements of this International Standard

Shall determine processes needed for QMS and their application throughout the organization. Shall

a) determine inputs required and outputs expected from these processes

b) determine sequence and interaction of these processes, eg Business or Process Flow Chart

c) determine and apply criteria and methods needed to ensure effective operation and control of these processes

4.4 QMS and its processes

4.4.1

d) determine resources needed for these processes and ensure their availability

e) assign responsibilities and authorities for these processes

f) address risks and opportunities as determined

g) evaluate these processes and implement any changes needed to ensure these processes achieve their intended results

h) Improve the process and QMS

4.4 QMS and its processes

* Refer to Company Process Flow Chart

4.4 QMS and its processes

4.4.2 Shall, to extent necessary,

a) maintain documented information to support the operation of its processes

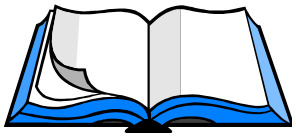
b) retain documented information to have confidence that processes are being carried out as planned

*Maintain documents such as procedures, drawings, specification, method statements etc

*Retain records such as test and inspection results

Documented information

Documents to be maintained shall include:



- **Procedures**
- **Quality Plan**
- **Work instructions / Method statements**
- **Singapore Standard, SS ISO 9001:2015**
- **National Quality Standard, CONQUAS 21**
- **Code of Practice**
- **Acts and Regulations**
- **Contract specifications and Drawing**

5 Leadership



5.1 Leadership and commitment
5.1.1 General
5.1.2 Customer focus

5.2 Policy
5.2.1 Establishing the quality policy
5.2.2 Communicating the quality policy

5.3 Organizational roles, responsibilities and authorities

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to QMS

a) take accountability for effectiveness of QMS

b) ensure quality policy and objectives are established and they are compactible with context and strategic direction

c) ensure integration of QMS requirements into business processes

d) promote use of process approach and risk-based thinking

e) ensure resources needed are available

f) communicate importance of effective quality management and of conforming to QMS requirements

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to QMS

g) ensure QMS achieve its intended results

h) engage, direct and support persons contributing to effectiveness of QMS

i) promote improvement

j) support other management roles to demonstrate their leadership as it applies to their areas of responsibility

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that

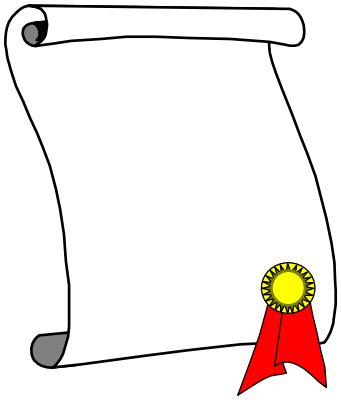
a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met

b) risks and opportunities that can affect conformity of products and services and ability to enhance customer satisfaction are determined and addressed

c) focus on enhancing customer satisfaction is maintained

5.2 Quality Policy

The intentions and directions of an organization related to quality as formally expressed by top management



5.2.1 Establishing the Quality Policy

Top management shall establish, implement and maintain a quality policy that

a) is appropriate to the purpose and context of the organization and support its strategic direction
b) provide a framework for setting quality objectives

c) includes a commitment to satisfy applicable requirements
d) includes a commitment to continual improvement of QMS

5.2.2 Communicating the Quality Policy

The quality policy shall

a) be available and be maintained as documented information
b) be communicated, understood and applied within the organization
c) be available to relevant interested parties as appropriate



5.2.2 Communicating the Quality Policy

* Refer to company Policy



5.3 Organizational roles, responsibilities and authorities

Top management shall ensure R&A for relevant roles are assigned, communicated and understood within the organization

Shall assign R&A to

a) ensure QMS conforms to ISO9001 requirements
b) ensure processes deliver their intended results
c) report on performance of QMS and on opportunities for improvement
d) ensure promotion of customer focus throughout the organization
e) ensure integrity of QMS is maintained when changes are planned and implemented

5.3 Organizational roles, responsibilities and authorities

* Refer to Company Organization Chart & Responsibilities and Authorities

6 Planning

6.1 Actions to address risks and opportunities
6.2 Quality objectives and planning to achieve them
6.3 Planning of changes



6.1 Actions to address risks and opportunities

6.1.1 Shall consider issues (4.1) and requirements (4.2) and determine the risks and opportunities that need to be addressed to

a) give assurance that QMS can achieve its intended results
b) enhance desirable effects

c) prevent or reduce undesirable effects

d) achieve improvement

6.1 Actions to address risks and opportunities

6.1.2 Shall plan

a) actions to address these risk and opportunities

b) how to
- integrate and implement actions into its QMS processes
- evaluate effectiveness of these actions

Actions taken to address risks and opportunities shall be proportionate to potential impact on conformity of products and services

6.1 Actions to address risks and opportunities

* Refer to IMS Checklists

6.2 Quality objectives and planning to achieve them

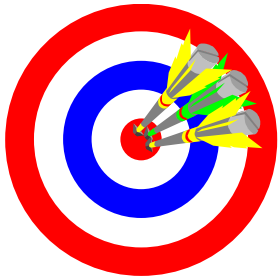
6.2.1 Shall establish quality objectives at relevant functions, levels and processes

Quality objectives shall

a) be consistent with quality policy
b) be measurable
c) take into account applicable requirements
d) be relevant to conformity of products and services and to enhance customer satisfaction
e) be monitored
f) be communicated
g) be updated

Quality Objectives

- Established at relevant functions and levels
- Measurable
- Consistent with Quality Policy

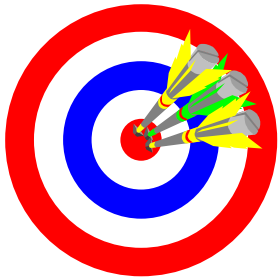


Set SMART Quality Objectives at relevant functions for your firm.

6.2 Quality objectives and planning to achieve them

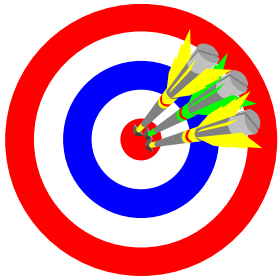
6.2.2 When planning how to achieve its quality objectives, organization shall determine

a) What will be done
b) What resources will be required
c) Who will be responsible
d) When it will be completed
e) How results will be evaluated



6.2 Quality objectives and planning to achieve them

* Refer to Company Objectives



6.3 Planning of changes

When organization determines the need for changes to QMS, changes shall be carried out in a planned manner

Shall consider

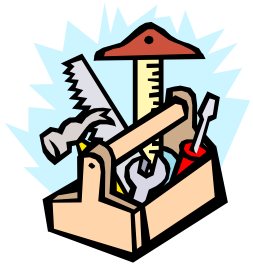
a) purpose of the changes and their potential consequences

b) integrity of the QMS

c) availability of resources

d) allocation or reallocation of R&A

7 Support

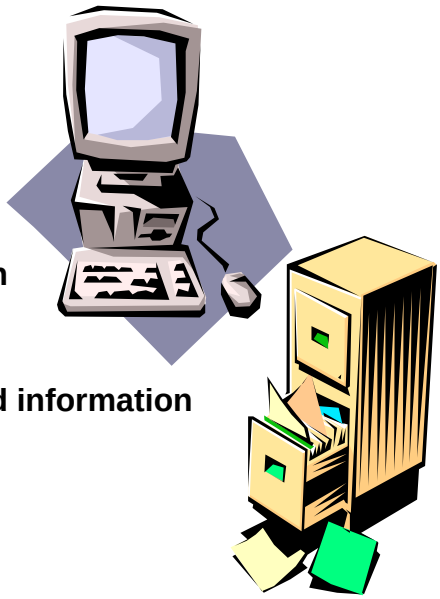


7.1 Resources
7.1.1 General
7.1.2 People
7.1.3 Infrastructure
7.1.4 Environment for the operation of processes

7.1.5 Monitoring and measuring resources
7.1.5.1 General
7.1.5.2 Measurement traceability

7.1.6 Organization knowledge

7 Support



7.2 Competence
7.3 Awareness
7.4 Communication

7.5 Documented information
7.5.1 General
7.5.2 Creating and updating
7.5.3 Control of documented information

7.1 Resources

7.1.1 General

- Determine and provide resources needed for establishment, implementation, maintenance and continual improvement of QMS

- Shall consider

a) capabilities of, and constraints on, existing internal resources

b) what need to be obtained from external providers

7.1.2 People

- Determine and provide persons necessary for the effective implementation of its QMS and for operation and control of its processes



7.1.3 Infrastructure

Determine, provide and maintain infrastructure necessary for the operation of its processes and to achieve the conformity of products and services.

Infrastructure can include:

a) Buildings and associated utilities
b) Equipment, including hardware and software)
c) Transportation services
d) Information and communication technology

7.1.3 Infrastructure

- BIM
- Engineering design and calculation software
- Computer and IT system
- Tower crane, crawler crane, mobile crane
- Concrete pump
- passenger/material hoist
- Material Receiving platform
- Forklift / Scissor Lift, generator etc

7.1.3 Infrastructure

- To ensure all infrastructure provided continue to meet the operational needs
- Establish and implement maintenance programme including the type and frequency of maintenance or servicing needed
- Should consider the safety and environmental impacts such as safety hazard, energy conservation, water, air and noise pollution

7.1.4 Environment for the operation of processes

Determine, provide and maintain environment necessary for the operation of its processes and needed to achieve conformity of products and services

* A suitable environment can be a combination of human and physical factors such as;

a) Social eg non-discriminatory, calm, non-confrontational
b) Psychological eg stress-reducing, burn-out prevention, emotionally protective
c) Physical eg temperature, heat, humidity, light, airflow, hygience, noise, weather, vibration, pollution

7.1.5 Monitoring and measuring resources

7.1.5.1 General

- Determine and provide resources needed to ensure valid and reliable results when monitoring or measuring is used to verify conformity of products and services to requirements
- Ensure resources provided:
  a) are suitable for specific type of monitoring and measurement activities being undertaken
  b) are maintained to ensure their continuing fitness for their purpose
- Retain appropriate documented information as evidence of fitness for purpose

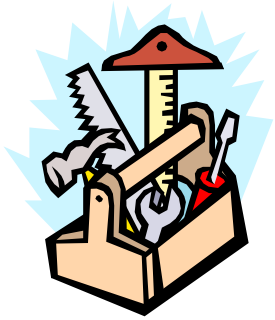
7.1.5.2 Measurement traceability

When measurement traceability is a requirement , or is considered essential part of providing confidence in validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified interval or prior to use against international or national standards
b) identified in order to determine their status eg label
c) safeguarded from adjustments, damage or deterioration that would invalidate calibration status and subsequent measurement results

7.1.5.2 Measurement traceability

- Determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall appropriate actions



Monitoring & Measuring Equipment

- Survey instruments
- Pressure gauge
- Dial gauge
- Weighing machine
- Tilt meter, inclinometer
- Gas meter, noise meter
- Voltmeter



7.1.6 Organizational knowledge



- Shall determine knowledge necessary for operation of its processes and to achieve conformity of products and services
- Shall maintain and make available knowledge
- Shall consider its current knowledge and determine how to acquire or access additional knowledge and required updates when addressing changing needs and trends

7.1.6 Organizational knowledge

Internal sources

-intellectual property, knowledge gained from experience, lessons learned from failures and successful projects etc



External sources

- standards, academic, conferences, seminar, gathering knowledge from customers or external providers

7.2 Competence

a) Determine necessary competence of persons doing work under its control that can affect performance and effectiveness of QMS

b) Ensure these persons are competent on the basis of appropriate education, training or experience

c) Take actions to acquire the necessary competence, and evaluate the effectives of actions taken

d) Retain appropriate documented information as evidence of competence

7.2 Competence

Applicable actions can include provision of training, mentoring, re-assignment of current employee, hiring or contracting of competent persons

7.3 Awareness

Shall ensure that persons doing work under its control are aware of

a) the quality policy
b) relevant quality objectives
c) their contribution to effectiveness of QMS, including benefits of improved performance
d) implications of not conforming with QMS requirements

7.4 Communication

Shall determine internal and external communications relevant to QMS, including

a) on what it will communicate
b) when to communicate
c) with whom to communicate
d) how to communicate
e) who communicate



7.5 Documented information

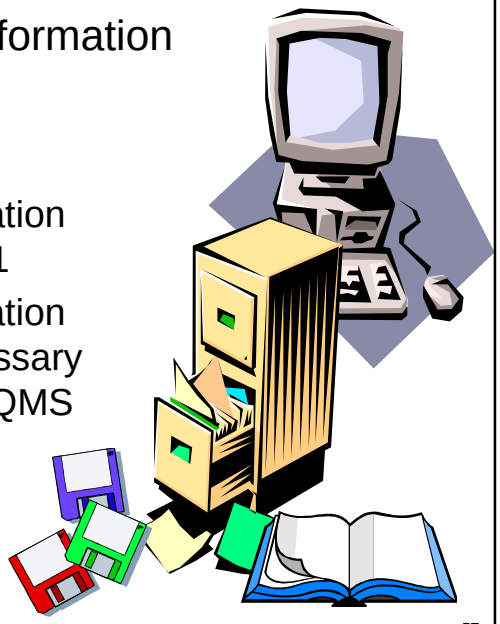
7.5.1 General

QMS shall include

a) documented information required by ISO9001

b) documented information determined as necessary for effectiveness of QMS





7.5.2 Creating and updating

When creating and updating documented information, organization shall ensure appropriate

a) identification and description eg title, reference

b) format (eg software version) and media (eg paper)

c) review and approval for suitability and adequacy



7.5.3 Control of documented information

7.5.3.1 Documented information shall be controlled to ensure

a) it is available and suitable for use, where and when it is needed
b) it is adequately protected (eg from loss of confidentiality, improper use or loss of integrity)

7.5.3 Control of documented information

7.5.3.2 For the control of documented information, organization shall address

a) distribution, access, retrieval and use
b) storage and preservation, including preservation of legibility
c) control of changes (eg version control)
d) Retention and disposition

- Documented information of external origin shall be identified as appropriate and controlled
- Documented information retained as evidence of conformity shall be protected from unintended alterations

8 Operation

8.1 Operational planning and control

8.2 Requirements for products and services
8.2.1 Customer communication
8.2.2 Determining the requirements for products and services
8.2.3 Review of the requirements for products and services
8.2.4 Changes to requirements for product and services

8 Operation

8.3 Design and development of products and services
8.3.1 General
8.3.2 Design and development planning
8.3.3 Design and development inputs
8.3.4 Design and development controls
8.3.5 Design and development outputs
8.3.6 Design and development changes
8.4 Control of externally provided processes, products and services
8.4.1 General
8.4.2 Type and extent of control
8.4.3 Information for external providers

8 Operation

8.5 Production and service provision
8.5.1 Control of production and service provision
8.5.2 Identification and traceability
8.5.3 Property belonging to customers or external providers
8.5.4 Preservation
8.5.5 Post-delivery activities
8.5.6 Control of changes

8.6 Release of products and services
8.7 Control of nonconforming outputs

8.1 Operational planning and control

Shall plan, implement and control processes needed to meet requirements for provision of products and services and to implement actions determined in Clause 6 by

a) determining the requirements for products and services
b) establishing criteria for
   - processes
   - acceptance of products and services
c) determining resources needed to achieve conformity to products and services requirements

8.1 Operational planning and control

d) implementing control of processes in accordance with criteria

e) determining, maintaining and retaining documented information
   - to have confidence that processes have been carried out as planned
   - to demonstrate conformity of products and services

Output of planning shall be suitable for operations. Shall control planned changes and review consequences of unintended changes, taking action to mitigate any adverse effects. Outsourced processes shall be controlled.

Operational planning

- **= project or construction planning for contractors**
- **= design planning for architects and engineers**
- **= production planning for manufacturers**

Project Quality Plan



A document specifying the processes of QMS and resources to be provided for a specific product, project or contract

Project Quality Plan

- Establish within one month from the date of project announcement
- Sets out the strategy to achieve desired quality in the project
- Should include:
  - **Project Information - Cost, Scope of Work**
  - **Organization - Project Team, Client's Representatives, other Consultants**
  - **Programme - Overall Programme, Authority Submissions & Status**

Project Quality Plan

- Should include:
  - **Project Records - List of Files and Drawings**
  - **Interfacing – Internal and External Parties**
  - **Design Inputs and Methodology – Client's Brief, Codes of Practice, Design Guide, Software**
  - **Environmental Conditions**
  - **Client's Requirements – Design Reports, Cost Estimates, Tender Reports etc**

8.2.1 Customer communication

Communication with customer shall include

a) providing information relating to products & services, i.e. M&E Consultancy, Due diligence Studies, Feasibility Studies

b) handling enquiries

c) obtaining customer feedback relating to services provided, including complaints

d) handling or controlling client's design requirements

e) establishing specific requirements for emergency actions where relevant

Customer Communication

Examples

reports, emails, letters, minutes of meeting, Architect / Engineer's instructions, confirmation of verbal instructions or issue of amendment drawings

*** Feedback include complaint → CA**



8.2.2 Determining requirements for services



Shall ensure

a) requirements are defined, including
   - applicable statutory and regulatory requirements
   - those considered necessary by organization

b) organization can meet claims for products and services it offers

8.2.3 Review of requirements for services

8.2.3.1 Shall ensure that it has ability to meet requirements for products and services. Shall conduct a review before committing to supply to customer:

a) requirements specified by customer, including requirements for delivery and post-delivery
b) requirement not stated by customer, but necessary for specified or intended use
c) requirements specified by organization
d) statutory and regulatory requirement
e) contract or order requirements differing from those previously expressed

8.2.3 Review of requirements for services

8.2.3.1

- Shall ensure service requirements differing from those previously defined are resolved
- Client's requirements shall be confirmed before acceptance, when client does not provide a documented statement of their requirements

8.2.3 Review of requirements for services

8.2.3.2 Shall retain documented information on



a) the results of the review
b) any new requirements for products and services e.g. additional work arising from change in work scope such as basement carpark changed to supermarket etc

8.2.4 Changes to requirements for services

Shall ensure that relevant documented information is amended, and that persons are made aware of the changed requirements when requirements for products and services are changed



8.3 Design and development of products and services

8.3.1 Shall establish, implement and maintain a design and development process that is appropriate to ensure subsequent provision of products and services i.e. Design brief, schematic design, design development, design reviews at various design stages, sign-off od design.

8.3.2 Design and development planning

In determining stages and controls for D&D, organization shall consider

a) nature, duration and complexity of D&D activities
b) required process stages, including applicable D&D reviews
c) required D&D verification and validation activities

8.3.2 Design and development planning

d) R&A involved in D&D process
e) internal and external resource needs for D&D
f) need to control interfaces between persons involved in D&D process
g) need for involvement of customers and users in D&D process
h) requirements for subsequent provision of products and services
i) level of control expected for D&D process by customers and other interested parties
j) documented information needed to demonstrate the D&D requirements have been met

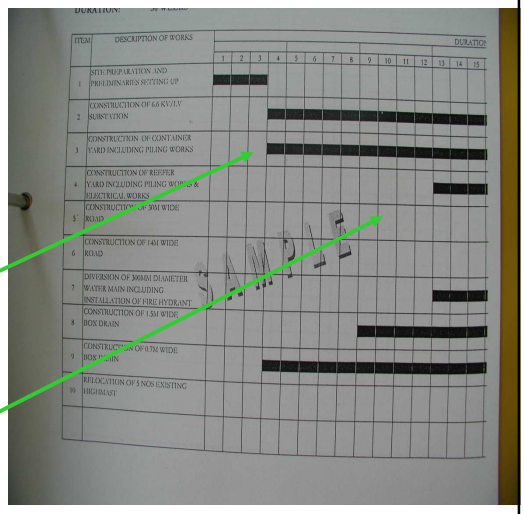
Design and Development Planning

A programme to control the design and development of a project

Review & verification of design

Validation of design calculations

Submission & Approval



Design and Development Planning

The need to control interfaces between persons involved in the design and development process

To manage design interfaces to ensure effective communication and clear assignment of responsibility

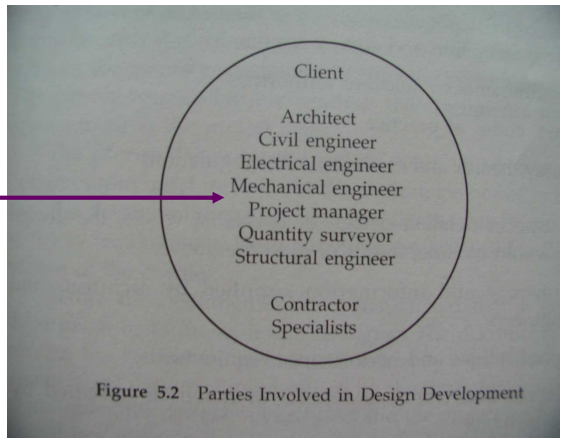


Figure 5.2 Parties Involved in Design Development

8.3.3 Design and development inputs

Shall determine requirements essential for specific types of developments such as Hospitals, Central Kitchens etc to be designed and developed. Shall consider

a) Client supplied requirements
b) functional and performance requirements
c) information derived from previous similar D&D activities
d) statutory and regulatory requirements
e) standards or CP
f) environment consideration
g) potential consequences of failure due to nature products and services

8.3.3 Design and development inputs

Inputs shall be adequate, complete and unambiguous. Conflicting inputs shall be resolved.

Shall retain documented information on D&D inputs

Design and Development inputs

- **Design Inputs Checklist to collate design inputs**
- **Review inputs for adequacy**
- **Incomplete, ambiguous or conflicting inputs need to be resolved**

Design Inputs Checklist

- Arch, C&S, M&E and Landscape Drawings
- Electrical Load
  - Power density W/m^2 for office
  - A/C temp 24°C$\pm$1°C
  - Hot water requirements
  - Recovery of waste heat
  - Energy conservation

8.3.4 Design and development controls

Shall apply controls to D&D process to ensure

a) results to be achieved are defined

b) reviews are conducted to evaluate if results of D&D meet requirements

c) verification activities are conducted to ensure that D&D outputs meet input requirements

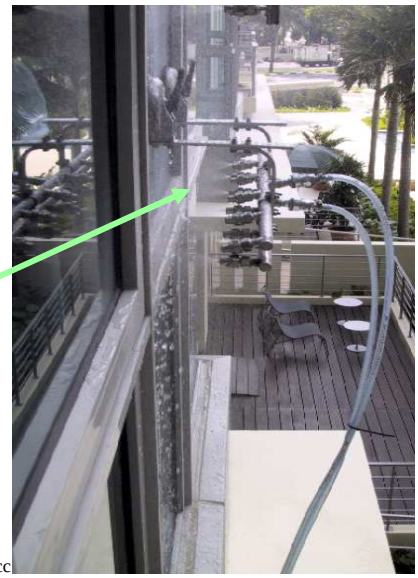
d) validation activities are conducted to ensure design software meets requirements for specified application or intended use

e) any necessary actions are taken on problems determined during reviews, verification and validation activities

f) documented information of these activities is retained

Validation Activities

– Testing your design on mock-up to check maintainability of M&E services above false ceiling and achievable clear head room



8.3.5 Design and development outputs



Shall ensure that D&D outputs

a) meet input requirements
b) are adequate for subsequent processes for provision of products and services
c) include or reference monitoring and measuring requirements and acceptance criteria
d) specify characteristics of products and services that are essential for their intended purpose and their safe and proper provision

Shall retain documented information on D&D outputs

Design and Development Outputs

- Provide output e.g. drawing, specification, model to enable verification against input requirements
- Approved for adequacy prior to release, design review, check prints of design calculations, tender drawings, tender specifications



8.3.6 Design and development changes

Shall identify, review and control changes made to ensure that there is no adverse impact on conformity to requirements



Shall retain documented information on

a) D&D changes
b) results of reviews
c) authorization of changes
d) actions taken to prevent adverse impacts

8.4 Control of externally provided processes, products and services

8.4.1 Shall ensure externally provided processes, products and services conforms to requirements

Shall determine controls to be applied when

a) products and services from external providers are intended for incorporation into its own products and services

b) products and services are provided directly to customers by external provider on behalf of organization

c) process or part of a process is provided by external provider as decided by organization

Shall determine and apply criteria for evaluation, selection, monitoring of performance, and re-evaluation of external provider based their ability to meet requirements

Shall retain documented information of these activities and any actions arising from evaluations

8.4.2 Type and extend of control

Shall ensure externally provided processes, products and services do not adversely affect its ability to deliver conforming products and services to customers

Shall

a) ensure externally provided processes remain within control of its QMS

b) define both controls that it intends to apply to external provider and those it intends to apply to resulting output

8.4.2 Type and extend of control

Shall

c) take into consideration

- potential impact of externally provided processes, products and services on its ability to meet customer and applicable statutory and regulatory requirements

- effectiveness of control applied by external provider

d) determine verification or other activities necessary to ensure that externally provided processes, products and services meet requirements

8.4.3 Information for external providers

Shall ensure adequacy of requirements prior to their communication to external provider

Shall communicate to external provider its requirements for

a) processes, products and services

b) approval of

- products and services
- methods, processes and equipment
- release of products and services



8.4.3 Information for external providers

Shall communicate to external provider its requirements for

c) competence, including any required qualifications of persons
d) external provider's interactions with organization
e) control and monitoring of external providers' performance to be applied by organization
f) verification or validation activities that organization or its customer, intends to perform at external providers' premises



8.5.1 Control of production and service provision

For a contractor,

Control of Production and Service Provision

=

Control of Construction Works

8.5.1 Control of production and service provision

Implement production and service provision under controlled conditions such as

a) availability of documented information that defines:
   - **characteristics of products to be produced, services to be provided or activities to be performed**
   - **results to be achieved**

b) availability and use of suitable monitoring and measuring resources

c) implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met

8.5.1 Control of production and service provision

d) use of suitable infrastructure and environment for operation of processes

e) appointment of competent persons, including any required qualification

f) validation, and periodic revalidation, of ability to achieve planned results of processes for production and service provision, where resulting output cannot be verified by subsequent monitoring or measurement eg method statement, mock up samples, testing on product etc

g) implementation of actions to prevent human error

h) implementation of release, delivery and post-delivery activities

8.5.2 Identification and traceability

- Shall use suitable means to identify outputs when necessary to ensure their conformity
  - e.g. test cubes, precast components, cladding panels, windows, unit no. or location, checklists etc
- Identify status of outputs with respect to monitoring and measurement requirements throughout production and service provision
- Control unique identification of outputs when traceability is a requirement and retain documented information to enable traceability

8.5.3 Property belonging to customers or external providers

- Exercise care in handling property belonging to clients or external providers while it is under its control or being used
- Identify, verify, protect and safeguard property provided for use or incorporation into the products and services
- When property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to customer or external and retain documented information on what has occurred

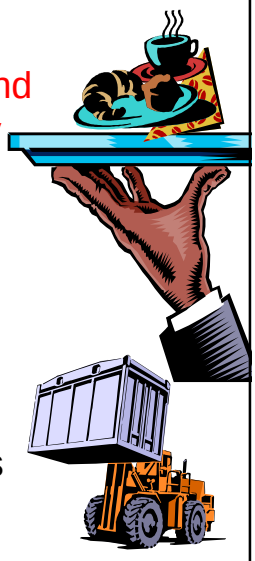
8.5.3 Property belonging to customers or external providers

Customer's or external provider's property can include :

- materials and components
- tools and equipment
- premises
- intellectual property
- personal data etc

8.5.4 Preservation

- Preserve outputs during production and service provision, to extent necessary to ensure conformity to requirements
- Preservation includes identification, handling, contamination control, packaging, storage, transmission or transportation, and protection



*Main objective is to prevent damages or deterioration of outputs

8.5.5 Post-delivery activities

- **Meet requirements for post-delivery activities associated with products and services**

- **In determining the extent of post-delivery activities that are required, organization shall consider:**

a) statutory and regulatory requirements
b) potential undesired consequences associated with its products and services
c) nature, use and intended lifetime of its products and services
d) customer requirements
e) customer feedback

8.5.5 Post-delivery activities

- Post-delivery activities include Amendment plans As-built drawings, O&M Manuals, Final Accounts, Defects Liability Period, defect warranty, maintenance services, supplementary services such as recycling or final disposal etc

- Rectification of defects & handling of complaints during Defects Liability Period (DLP)



8.5.6 Control of changes

- Review and control changes for production or service provision, to the extent necessary to ensure continuing conformity to requirements
- Retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review

8.6 Release of products and services

- Implement planned arrangements, at appropriate stages, to verify that products and services requirements are met
- Release to customer shall not proceed until planned arrangements have been satisfactorily completed, unless otherwise approved by relevant authority and, as applicable, by customer



8.6 Release of products and services

- **Retain documented information on the release of products and services**

- **Information shall include:**

a) evidence of conformity with the acceptance criteria

b) traceability to person(s) authorizing the release

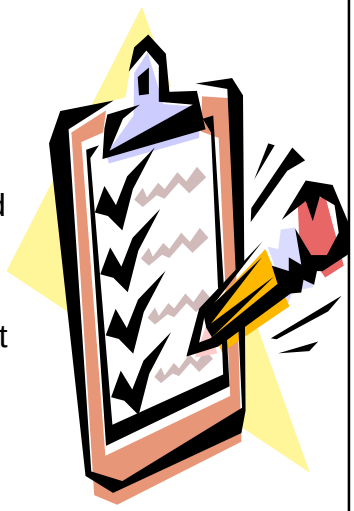


8.6 Release of products and services

- **Ensure materials and products produced at all stages conform to specifications**
- **3 stages of QC**
  - **receiving inspection & testing**
  - **in-process inspection & testing**
  - **final inspection & testing**
- **Based on documented procedures or quality plan for that project**

Get it Right the First time

- Any NCs noted should be recorded
- Common misconception to record only when items passed the inspection
- To maintain inspection and test records



8.7 Control of nonconforming outputs

8.7.1

- Identify and control outputs that do not conform to their requirements to prevent unintended use or delivery
- Take appropriate action based on nature of NC and its effect on conformity of products and services including those detected after delivery of products, during and after provision of services



8.7 Control of nonconforming outputs

8.7.1

- **Deal with NC outputs in one or more of the following ways:**

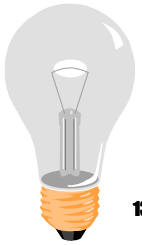
a) correction

b) segregation, containment, return or suspension of provision of products and services

c) informing the customer

d) obtaining authorization for acceptance under concession

- **Verify conformity to requirements when NC outputs are corrected**



8.7 Control of nonconforming outputs

8.7.2

- Retain documented information that:



a) describes the NC

b) describes the actions taken

c) describes any concessions obtained

d) identifies the authority deciding the action in respect of the NC

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation
9.1.1 General
9.1.2 Customer satisfaction
9.1.3 Analysis and evaluation

9.2 Internal audit

9.3 Management review
9.3.1 General
9.3.2 Management review inputs
9.3.3 Management review outputs



9.1 **Monitoring, measurement, analysis and evaluation**

9.1.1 General - Shall determine

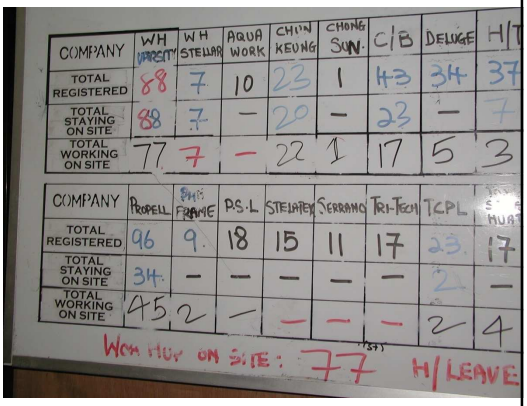
a) what needs to be monitored and measured
b) methods for monitoring and measurement, analysis and evaluation needed to ensure valid results
c) when monitoring and measuring shall be performed
d) when results from monitoring and measurement shall be analyzed and evaluated



Shall evaluate performance and effectiveness of QMS and retain appropriate documented information as evidence of the results

9.1 Monitoring, measurement, analysis and evaluation

- **Apply suitable methods for monitoring and measuring**
  - **Product quality**
  - **Cycle time**
  - **Reaction time**
  - **Cost reduction**
  - **Waste reduction**
  - **Efficiency and effectiveness of people or processes**
- **Serial No. of instrument to be recorded on the inspection / T&C form for traceability**



9.1.2 Customer Satisfaction

- **Monitor customers' perceptions of degree to which their needs and expectation have been fulfilled**
- **Determine methods for obtaining, monitoring and reviewing this information. Examples:**
  - **Customer surveys**
  - **Customer feedback on products and services** (conduct yearly feedback for long term project & at the end of project completion of all projects)
  - **Meeting with customers**
  - **Market-share analysis**
  - **Compliments**
  - **Warranty claims**
  - **Dealer reports**

9.1.3 Analysis and evaluation

- **Analyze and evaluate appropriate data and information arising from monitoring and measurement**
- **Results of analysis used to evaluate**

a) conformity of products and services
b) degree of customer satisfaction
c) performance and effectiveness of QMS
d) if planning has been implemented effectively
e) effectiveness of actions taken to address risks and opportunities
f) performance of external providers
g) need for improvements to QMS



9.1.3 Analysis and evaluation

Methods to analyze data can include statistical techniques.

- Flowchart
- Checklist
- Histogram
- Control chart
- Pareto chart
- Scatter diagram
- Cause & effect diagram
- etc



9.2 Internal Audit

9.2.1 Conduct internal audits at planned intervals to provide information on whether QMS



a) conforms to:
– own requirements for its QMS
– to ISO9001 requirements

b) is effectively implemented and maintained

9.2 Internal Audit

9.2.2

a) Plan, establish, implement and maintain audit programme including frequency, methods, responsibilities, planning requirements and reporting.

Shall consider
– **importance of the processes**
– **Changes affecting organization**
– **results of previous audits**



9.2.2 Internal Audit



b) Define audit criteria and scope for each audit

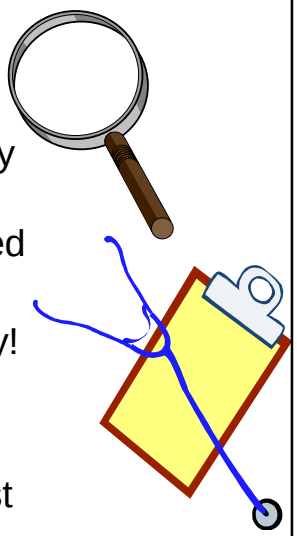
c) Select auditors and conduct audits to ensure objectivity and impartiality of audit process

d) Ensure the results of the audits are reported to relevant management

e) Take appropriate correction and corrective actions without undue delay

f) Retain documented information as evidence of implementation of the audit programme and audit results

During the Audit



- All NCs shall be recorded & rectified without undue delay by the person responsible for that particular area within the agreed period
- To state what you observe only!
- Auditor to follow up on rectification action taken
- All internal Quality Auditor must be trained

9.3 Management Review

9.3.1 General

A formal review by the top management to ensure the continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization



9.3.2 Management review inputs

a) Status of actions from previous reviews
b) Changes in external and internal issues relevant to QMS
c) Information on performance and effectiveness of QMS
   - Customer satisfaction and feedback from interested parties
   - Extent to which quality objectives have been met
   - Process performance & conformity of product and services
   - NCs and corrective actions
   - Monitoring and measurement results
   - Audit results
   - Performance of external providers

9.3.2 Management review inputs

d) Adequacy of resources

e) Effectiveness of actions taken to address risks and opportunities

f) Opportunities fro improvement

9.3.3 Management review outputs

Any decisions and actions related to:

a) opportunities for improvement
b) any need for changes to QMS
c) resource needs

Shall retain documented information as evidence of the results of management reviews

10. Improvement

10.1 General

10.2 Nonconformity and corrective action

10.3 Continual improvement



10.1 General



- **Determine and select opportunities for improvement**
- **Implement necessary actions to meet customer requirements and enhance customer satisfaction by**

a) improve products and services to meet requirements and to address future needs and expectations

b) correct, prevent or reduce undesired effects

c) improve performance and effectiveness of QMS

10.1 General



Examples of improvement can include:

- **correction**
- **corrective action**
- **continual improvement**
- **breakthrough change**
- **innovation**
- **re-organization**

10.2 Nonconformity and Corrective action

10.2.1 When NC occurs including complaints

a) React to NC

- Take action to control and correct it
- Deal with the consequences

b) Evaluate the need for action to eliminate the causes of the NC so it does not recur or occur elsewhere

- Review and analyze NC
- Determine the causes of NC
- Determine if similar NC exist, or could potentially occur

10.2 Nonconformity and Corrective action

10.2.1 When NC occurs including complaints

c) Implement any action needed
d) Review effectiveness of any CA taken
e) Update risks and opportunities determined during planning if necessary
f) Make changes to QMS if necessary

CA shall be appropriate to the effects of the NC encountered.

10.2 Nonconformity and Corrective action

10.2.2 Retain documented information as evidence of

a) nature of the NC and any subsequent actions taken

b) results of any CA



10.3 Continual Improvement

- Continually improve the suitability, adequacy and effectiveness of the QMS

- Consider the results of analysis and evaluation, and outputs from management review to determine if there are needs or opportunities to be addressed as part for continual improvement

*Sources of information include: Lost business, market analysis / trend, output from data analysis, measurements of processes and product